

# Comments on the NTP's Report on Carcinogens (RoC) Process

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# Recommendations

- Strengthen the scientific quality
- Enhance public participation processes in the development of RoC actions
- Clarify listing/delisting criteria used for the RoC

# Scientific Quality

- The foundation of RoC listings and delistings
  - comprehensive and thorough review and interpretation of the best available science
  - scientific experts need to be involved
  - conducted in a manner that fosters scientific dialog
  - transparent decision making, open meetings and stakeholder involvement
- Any changes to the RoC contemplated by NTP should be focused on ensuring these fundamental principles are enhanced
- NTP's efforts to revise the RoC process will be advanced by activities to address Data Quality and Peer Review directives of OMB

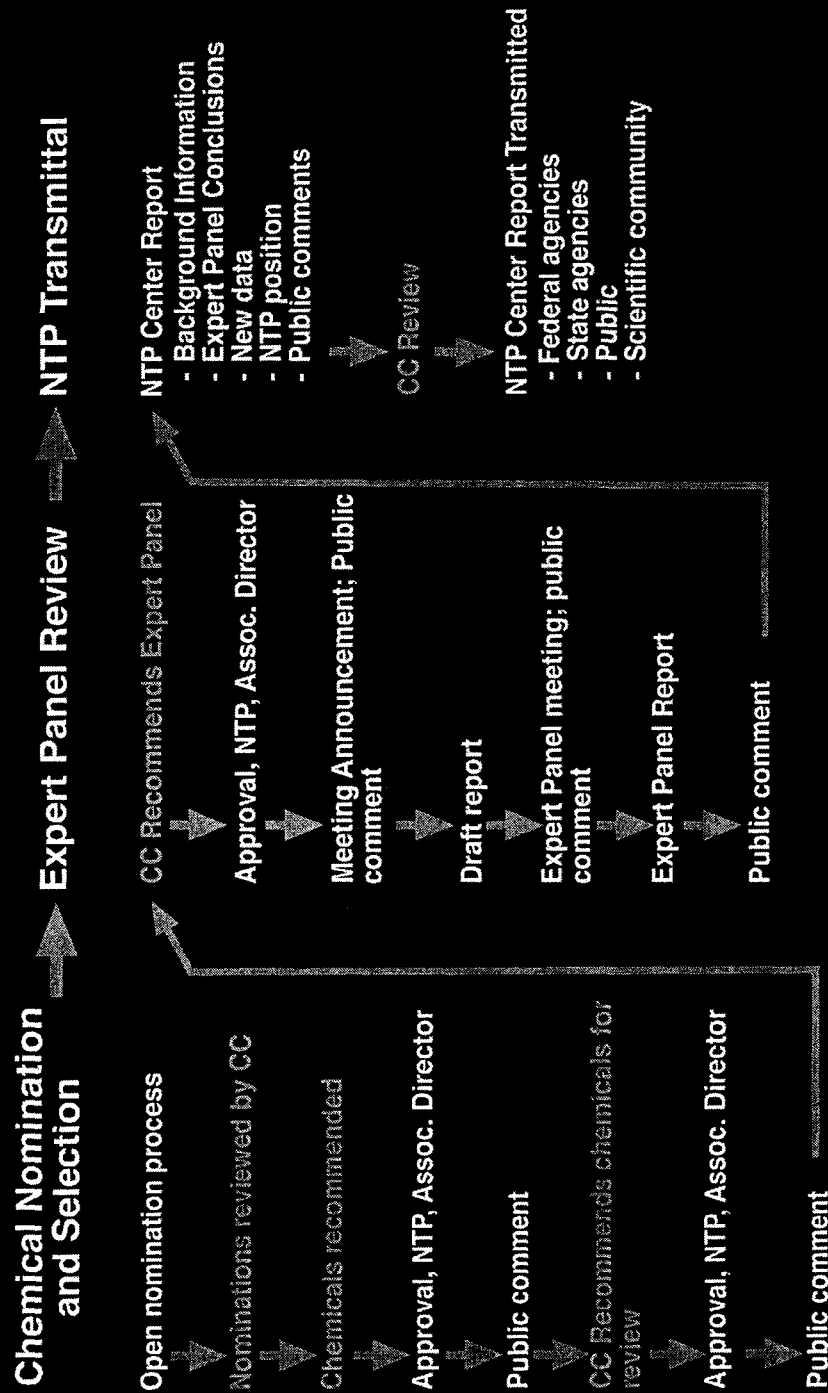
# Public & Stakeholder Participation

- Open & transparent process
- Adequate time to engage
- Opportunity for meaningful input at appropriate points
- Recognition that comments & interchange is considered fully

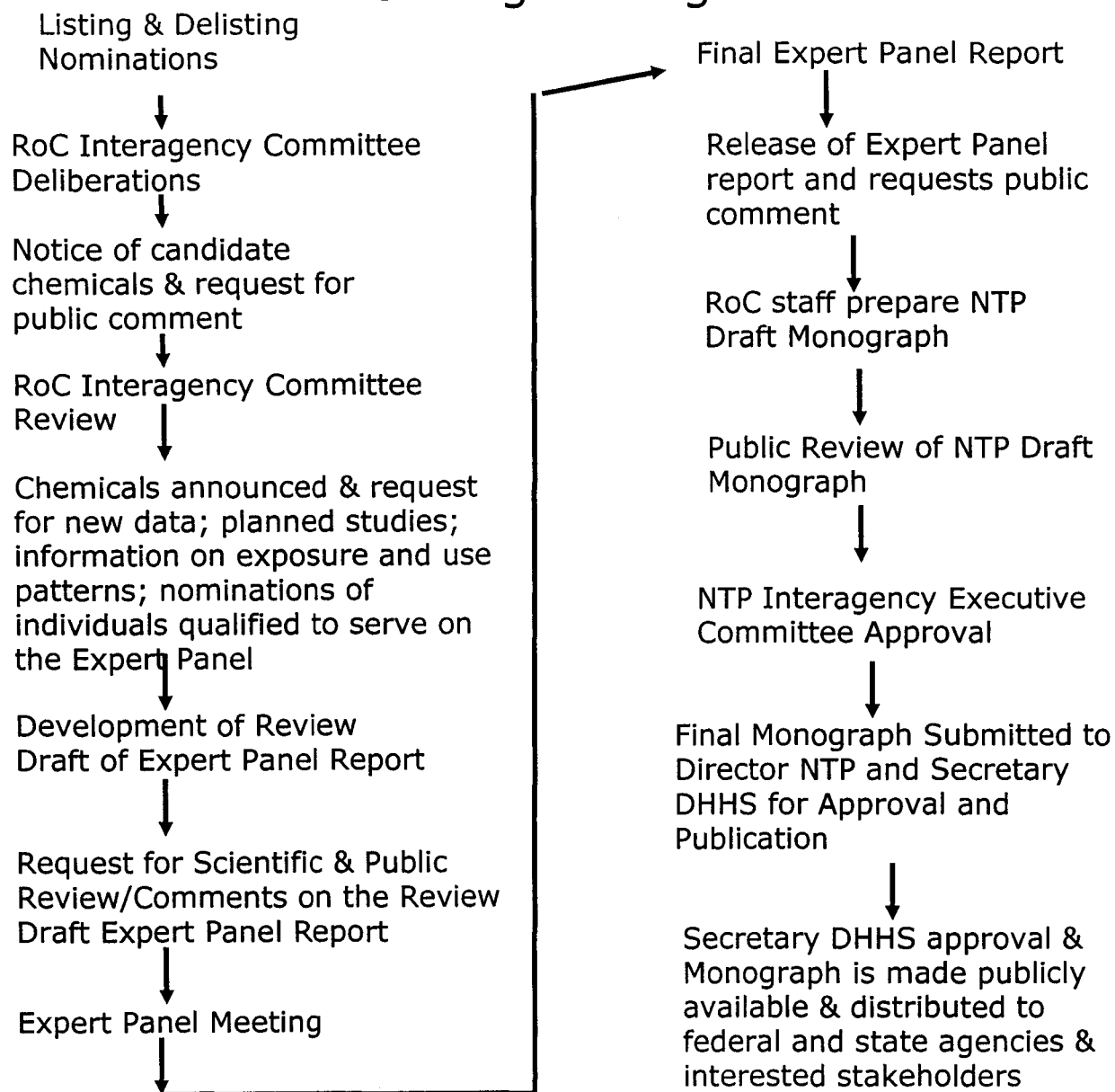
# ACC's Recommendations

- NTP consider adapting and building on the interactive scientific model put into practice in the CERHR process
- Adaptation of the CERHR process:
  - Comprehensive & thorough background document
  - Participation in drafting/writing document by subject-matter experts
  - Opportunity for meaningful scientific input early on in the process: latest studies, mode of action data, etc.

# — Process — NTP Center for the Evaluation of Risks to Human Reproduction



## Recommended Process NTP Consider for Strengthening the RoC



# Criteria for Listing/Delisting

- “Known to be a human carcinogen” -- determination should only be made if there is sufficient evidence of carcinogenicity from epidemiological or clinical studies that indicate a causal relationship between exposure to the agent and human cancer.
- A clear distinction between “known to be a human carcinogen” and “reasonably anticipated to be a human carcinogen” is sound public policy.
- Mechanistic or other scientific information should be used in reaching a determination of “reasonably anticipated to be (or not to be) a human carcinogen”